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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,709	03/08/2001	Andrew C. Lam	ARC2865N1	1161

7590 06/18/2004

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EXAMINER	
FAY, ZOHREH A	
ART UNIT	**PAPER NUMBER**
1614	25

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/802,709	Applicant(s) LAM ET AL.	
	Examiner Zohreh Fay	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37 and 46-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37 and 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 37and 46-50 are presented for examination.

Claims 37 and 46-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Vas-Cath Inc V. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for the purposes of written description inquiry, whatever is now claimed." Vas-Cath inc. v.Mahurkar, 19 USPQ 2d at 1117.

Applicant's invention is drawn to a method of treating ADD or ADHD in a patient, wherein the method comprises administering a pharmaceutically acceptable composition comprising 100 ng to 500 mg of methylphenidate and a pharmaceutically acceptable carrier to a patient in a manner that achieves a substantially ascending methylphenidate plasma drug concentration over a period of about 5.5 hours following said administration. However, the claimed concentration of 100 ng to 500 mg is not disclosed within the instant specification. These claims were submitted by preliminary amendment but the declaration fails to refer to the submission of any preliminary amendment. The originally filed claims do not include the above noted concentration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37 and 46-48 are rejected under 35 U.S.C. 102 (b) as being anticipated by J.W Hubbard et al. (J. of Pharmaceutical Sciences, Vol 78, No.11, November 1989, 944-947.

The claims are drawn to a method for treating Attention-deficit disorder (ADD) or Attention-Deficit Hyperactivity Disorder (ADHD) in a patient administering a pharmaceutically acceptable composition comprising 100 ng to 500 mg of methylphenidate (MPH) to achieve a substantially ascending methylphenidate plasma drug concentration over a time period of 5.5 hours (claim 37). The specification (lines 1-8) defines "ascending release rate" as "a periodic release rate that is increased over immediately-preceding periodic release rate, where the periodic intervals are the same. For example, when the quantity of drug released from a dosage form is measured at hourly intervals and the quantity of drug released during the fifth hour following administration (determined at t=5hours) is greater than the quantity of drug released during the dosage form during the fourth hour following administration (determined at t= 4hours), an ascending release rate from the fourth hour to the fifth hour has occurred."

Hubbard et al. Teach the administration of methylphenidate is widely used to treat children with ADD (page 944) and that in his study all children were administered 20 mg of MPH-SR (sustained release). The curve representing 1-

MPH from patient profile 2, teaches an ascending sustained plasma

concentration up to 6 hours.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37 and 46-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15 and 88-95 of copending Application No. 09/253,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming a method of treating ADD or ADHD comprising administrating methylphenidate at the ascending release rate. The dosage form comprises the same range of 100 ng to 500 mg and the time periods are equally covered.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200